

AZ (I<sub>c</sub>) and the applied pulsing current is applied for greater than or equal to a critical time period

(t<sub>c</sub>).

## REMARKS

### Objection to the Specification

The examiner has indicated that there was no abstract filed. Our records indicated that an abstract was filed and is found on page 35. Please find enclosed a copy of Form PCT/DO/EO/903 indicating that a copy of the international application in English has been received by the United States Patent Office. Please also find enclosed a copy of the first page of the published PCT application showing the abstract. We have included a copy of page 35 which includes an identical abstract to that shown on the PCT publication of the same application.

### Rejection under 35 USC § 102

The Examiner has rejected claims 1-3, 6-16, 18-21, and 24-26 as being anticipated by Tapper, USPN 5,224,927. Amendments have been made herein to independent claims 1 and 14 in which the pulsing current is more particularly claimed as a pulsing DC current. Because Tapper recites only an AC current, it does not anticipate the instant claims.

The Examiner makes reference to waveforms having segments and that the segments can be of any number and that the segments can start and stop wherever and whenever "one of ordinary skill wishes to interpret them". Applicant is puzzled by this discussion as there is no language about "segments" in any of the claims. Further, the Examiner asserts that "...applicant is claiming mathematical calculations of the raw data..."

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Both independent claims 1 and 14 include language in which the delivery efficiency (E) is increased when the current density is equal to or greater than a critical current density level ( $I_c$ ) and the pulsing current is applied for a period equal to or greater than a critical time period ( $t_c$ ). In each of claims 1 and 14, this language is found in lines 11-14 of the claim. Though this language requires mathematical calculations be performed in order to practice the claimed invention, applicant is claiming relationships between the parameters when some parameters meet specified criteria. Applicant is not claiming just mathematical calculations.

The Examiner has not in any way addressed the claim language pertaining to the relationships between the delivery efficiency (E), the critical current density ( $I_c$ ) and the critical time period ( $t_c$ ). As all the elements of the Applicants' claims are not found in the cited reference, the § 102 rejection cannot be sustained. Applicant respectfully requests that the § 102 rejection over Tapper be withdrawn.

#### **Rejection under 103(a)**

The Examiner has rejected claims 4-5, 17, and 22-23 over Tapper, USPN 5,224,927 in view of Chien, USPN 5,042,975 or Tapper in view of Theeuwes, USPN 5,298,017.

As previously discussed in the section addressing the § 102 rejection, there is no disclosure in Tapper regarding the relationship between delivery efficiency (E), critical current density ( $I_c$ ) and critical time period ( $t_c$ ). In addition there is no such disclosure in any of the cited references. Further, the Examiner has made no assertion that Applicants' device or method would be known to one skilled in the electrotransport arts. Therefore the Examiner has failed to make a *prima facie* case of obviousness and the § 103 rejection should be withdrawn.

### Summary

Applicants having addressed all of the Examiner's rejections and objections either by the amendments or remarks contained herein. Applicants assert that the claims are now in condition for allowance, notice of which is earnestly solicited.

Respectfully submitted,

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By: Owen J. Bates

Owen J. Bates  
Registration No. 40,346

ALZA Corporation  
1900 Charleston Road  
(P.O. Box 7210)  
Mountain View, CA 94043  
Telephone: (650) 564-7867 Fax: (650) 564-2195



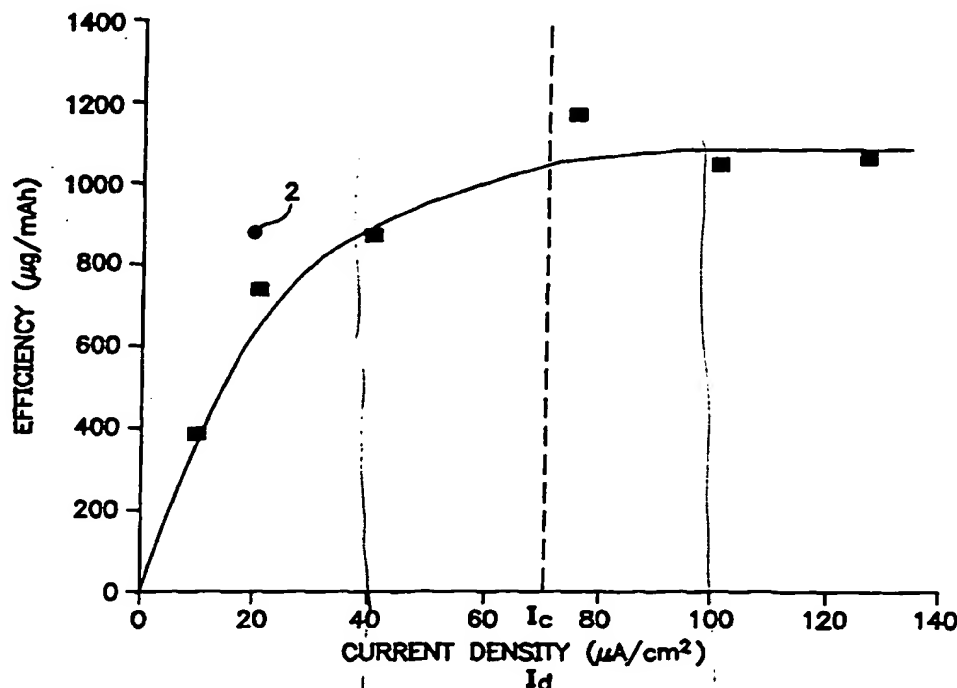


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61N 1/32</b>		A1	(11) International Publication Number: <b>WO 96/40364</b>
			(43) International Publication Date: 19 December 1996 (19.12.96)
(21) International Application Number: PCT/US96/09989 (22) International Filing Date: 7 June 1996 (07.06.96) (30) Priority Data: 08/483,069 7 June 1995 (07.06.95) US (71) Applicant (for all designated States except US): ALZA CORPORATION [US/US]; 950 Page Mill Road, P.O. Box 10950, Palo Alto, CA 94303-0802 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): PHIPPS, J., Bradley [US/US]; 5309 Ximines Lane, Plymouth, MN 55442 (US). LATTIN, Gary, A. [US/US]; 6927 145th Avenue, Forest Lake, MN 55025 (US). HAAK, Ronald, P. [US/US]; 2647 Alpine Road, Menlo Park, CA 94025 (US). THEEUWES, Felix [BE/US]; 27350 Altamont Road, Los Altos Hills, CA 94022 (US). GUPTA, Suneel [IN/US]; 4028 Farm Hill Road, No. 5, Redwood City, CA 94061 (US). (74) Agents: MILLER, D., Byron et al.; Alza Corporation, 950 Page Mill Road, P.O. Box 10950, Palo Alto, CA 94303-0802 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.	

COPY

(54) Title: ELECTROTRANSPORT AGENT DELIVERY METHOD AND APPARATUS



(57) Abstract

An electrotransport agent delivery device (10) for delivering a therapeutic agent through intact skin, and a method of operating same, is provided. The device applies a pulsing electrotransport current wherein current pulses have a magnitude above a critical level ( $I_c$ ) at which the skin is transformed into a higher electrotransport delivery efficiency (E) etc. Most preferably the length of the applied current pulses is at least 5 msec and preferably at least 10 msec.

UNITED STATES OF AMERICA

Address: ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D.C. 20540

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CHRISTOPHER J. ROGERS  
ALZA CORPORATION  
950 PAGE MILL ROAD  
PO BOX 10950  
PALO ALTO CA 94303-0802

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**NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371  
AND 37 CFR 1.494 OR 1.495**

1. The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as ☐ a Designated Office (37 CFR 1.494), ☒ an Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is **ACCEPTED** for national patentability examination in the United States Patent and Trademark Office.

2. The United States Application Number assigned to the application is shown above and the relevant dates are:

**17 NOV 1997**

**17 NOV 1997**

35 U.S.C. 102(e) DATE

DATE OF RECEIPT OF  
35 U.S.C. 371 REQUIREMENTS

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A Filing Receipt (PTO-103X) will be issued for the present application in due course. THE DATE APPEARING ON THE FILING RECEIPT AS THE "FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371(C) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE. The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

3. ☒ A request for immediate examination under 35 U.S.C. 371(f) was received on **17 NOV 1997** and the application will be examined in turn.

4. The following items have been received:

- ☒ U.S. Basic National Fee.
- ☒ Copy of the international application in:
  - ☐ a non-English language.
  - ☒ English.
- ☒ Translation of the international application into English.
- ☒ Oath or Declaration of inventor(s) for DO/EO/US.
- ☒ Copy of Article 19 amendments. ☐ Translation of Article 19 amendments into English.
 

The Article 19 amendments ☐ have ☐ have not been entered.
- ☒ The International Preliminary Examination Report in English and its Annexes, if any.
- ☒ Translation of Annexes to the International Preliminary Examination Report into English.
 

The Annexes ☒ have ☐ have not been entered.
- ☐ Preliminary amendment(s) filed \_\_\_\_\_ and \_\_\_\_\_.
- ☒ Information Disclosure Statement(s) filed \_\_\_\_\_ and \_\_\_\_\_.
- ☐ Assignment document.
- ☐ Power of Attorney and/or Change of Address.
- ☐ Substitute specification filed \_\_\_\_\_.
- ☐ Verified Statement Claiming Small Entity Status.
- ☐ Priority Document.
- ☒ Copy of the International Search Report ☐ and copies of the references cited therein.
- ☐ Other:

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.51).

*Rulette Kidwell*  
Paralegal Specialist  
Telephone: (703) 305-3656

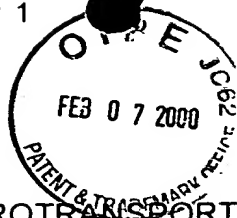
FORM PCT/DO/EO/903 (September 1996)

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ALZA CORPORATION

*08/952,368  
part 17 #10*ELECTROTRANSPORT AGENT DELIVERY METHOD AND APPARATUSABSTRACT

An electrotransport agent delivery device (10) for delivering a therapeutic agent through intact skin, and a method of operating same, is provided. The device applies a pulsing electrotransport current wherein current pulses have a magnitude above a critical level ( $I_c$ ) at which the skin is transformed into a higher electrotransport delivery efficiency (E) state. Most preferably the length of the applied current pulses is at least 5 msec and preferably at least 10 msec.

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